

REMARKS

Claims 30-32 have been added. Claims 12-29 have been cancelled. Claims 1-11 and 30-32 are pending.

Claims 30-32 have been added to emphasize that those embodiments directed to administration of nutritional products, including those in powder or ready-to-feed liquid forms. Support for this amendment can be found in Applicants' specification at page 19, lines 15-17; page 20, lines 3-5; and page 25, lines 15-18.

Rejection under 35 USC 102

Claims 1-4, 7 and 9 have been rejected under 35 USC 102(b) as being anticipated by WO 87/03198 (Bogentoft) in light of each of the following references:

1. The Merck Index (Monograph 5383, page 867) (Merck)
2. Brenna JT, Efficiency of Conversion of Linolenic Acid to Long Chain n-3 Fatty acids in Man, Current Opinion in Clinical Nutrition and Metabolic Care, 5(2):127-132, March 2002, Abstract (Brenna)
3. US Patent 5,709,888 (Gil)

Applicants respectfully traverse this rejection.

Bogentoft discloses capsules, tablets, and microcapsules having a coating resistant to gastric juices that dissolves only in the ileum, the distal portion of the small intestine (page 1, par. 1). The hydrophobic substances are thus delivered to the ileum, at which point they interact with specific ileum receptors to induce satiety (page 1, par. 3).

Merck, Brenna, and Gil were cited by the examiner to show that some of hydrophobic substances disclosed by Bogentoft may inherently include the triacylglycerols of n-3 polyunsaturated fatty acids as recited in Applicants' claims.

Applicants submit that Bogentoft fails to disclose composition other than enterically coated dosage forms designed to deliver unabsorbed material directly to the ileum

(Bogentoft, p. 1, par. 1). Applicants' method, by contrast, is clearly not directed to enterically coated materials. None of the products disclosed by Applicants are enteric coated.

Bogentoft also fails to disclose nutritional products comprising fat, protein, and carbohydrates. Claims 30-32, by contrast, are limited to nutritional products comprising fat, protein, and carbohydrates.

Bogentoft also discloses administration of compositions that are not dissolved in the stomach and go directly to the ileum unabsorbed (Bogentoft, p. 1, par. 3). Applicants' method, by contrast, involves enteral administration of nutritional products or other compositions directly to the stomach (Specification, p. 30, lines 30 and 31).

Although Bogentoft discloses a myriad of hydrophobic substances, it fails to specifically disclose selection of the triacylglycerol esters of n-3 polyunsaturated fatty acids to which all of the present claims are limited. Applicants found that oral administration of these fatty acid esters results in appetite reduction, whereas n-6 fatty acids result in an increase in appetite (as measured by food intake). Nowhere does Bogentoft disclose such a selection.

Bogentoft also fails to disclose any methods directed to the administration of triacylglycerol esters of docosahexaenoic acid, specifically. Claims 2, 3, and 8-11 are limited to docosahexaenoic acid. Although the examiner points out that alpha-linolenic acid as disclosed by Bogentoft may be partially converted to docosahexaenoic acid in the body, the fact still remains that the above-claims recite administration of docosahexaenoic acid, not a precursor thereof.

In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejections under 35 USC 102.

Rejection under 35 USC 103

Claims 1-1 have been rejected under 35 USC 103(a) as unpatentable over WO 87/03198 (Bogentoft) in view of Merck, Brenna, and Gil. Applicants respectfully traverse this rejection.

Bogentoft as the primary reference is summarized above.

The secondary references as noted above were only cited by the examiner to show that some of the hydrophobic substances disclosed by Bogentoft may inherently include the triacylglycerol esters of n-3 polyunsaturated fatty acids as recited in Applicants' claims.

Bogentoft fails to disclose or suggest any composition other than enterically coated dosage forms designed to deliver unabsorbed hydrophobic materials directly to the ileum (Bogentoft, p. 1, par. 1). Bogentoft teaches that direct delivery of unabsorbed hydrophobic materials to the ileum, effectively bypassing gastric dissolution and digestion, results in increased satiety (Bogentoft, p. 1, pars. 2 and 3). The present claims, by contrast, are directed to conventional oral or enteral administration, which includes initial exposure to gastric contents (Specification, p. 30, lines 30 and 31), not enteric coated delivery of a material to the distal small intestine.

Bogentoft also fails to disclose or suggest nutritional products comprising fat, protein, and carbohydrates. Claims 30-32, by contrast, are limited to nutritional products comprising fat, protein, and carbohydrates. Applicants submit that there would be little point in consuming an enteric coated nutritional product, even if such a product were possible, to deliver undigested and unabsorbed food to the distal small intestine.

Bogentoft also fails to disclose or suggest the *selection* of triacylglycerol esters of n-3 polyunsaturated fatty acids to which all of the present claims are limited. Applicants discovered that oral administration of these fatty acid esters results in appetite reduction. Bogentoft, by contrast, teaches appetite reduction by administering any hydrophobic material directly to the ileum, i.e., by enterically

coating the hydrophobic material. Nowhere does Bogentoft give the skilled artisan any hint that triacylglycerol esters of n-2 polyunsaturated fatty acids could be administered without enteric coating, without by-passing much of the gastrointestinal tract, to achieve increased satiety.

As to the secondary references, they were only cited to help define the scope of potential hydrophobic materials disclosed by Bogentoft, none of which actually provide the skilled artisan with any motivation to use triacylglycerol esters of n-2 polyunsaturated fatty acids for increased satiety.

In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejections under 35 USC 103.

Conclusion

Applicants respectfully request reconsideration of this application and allowance of claims 1-11 and 30-32.

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